

## PATENT COOPERATION TREATY

## PCT

REC'D 07 MAY 2001

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

IPO

PCT

(PCT Article 36 and Rule 70)

|   |   |   |
|---|---|---|
| Applicant's or agent's file reference<br>MWH-0031PCT  | <b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |   |
| International application No.<br>PCT/US00/06502   | International filing date (day/month/year)<br>10 MARCH 2000   | Priority date (day/month/year)<br>12 MARCH 1999 |
| International Patent Classification (IPC) or national classification and IPC<br>IPC(7): C12Q 1/68; C07H 21/04 and US Cl.: 435/6, 536/23.5 |   |   |
| Applicant<br>UNIVERSITY OF CINCINNATI   |   |   |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of — sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

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|--|--|
| Date of submission of the demand<br><br>11 OCTOBER 2000  | Date of completion of this report<br><br>26 MARCH 2001   |
| Name and mailing address of the IPEA/US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231 | Authorized officer<br><b>TERRY J. DEY</b><br><b>PARALEGAL SPECIALIST</b><br>SCOTT HOUTTEM<br><b>TECHNOLOGY CENTER 1600</b> |
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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/06502

**I. Basis of the report**1. With regard to the **elements** of the international application:\*☒ the international application as originally filed☒ the description:pages 1-18, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_☒ the claims:pages 19-20, as originally filedpages NONE, as amended (together with any statement) under Article 19pages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_☒ the drawings:pages 1-6, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_☒ the sequence listing part of the description:pages 1-4, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:☒ contained in the international application in printed form.☒ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. ☒ The amendments have resulted in the cancellation of:☒ the description, pages NONE☒ the claims, Nos. NONE☒ the drawings, sheets/fig NONE5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/06502

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

## 1. statement

|                               |                    |     |
|-------------------------------|--------------------|-----|
| Novelty (N)                   | Claims <u>1-14</u> | YES |
|                               | Claims <u>NONE</u> | NO  |
| Inventive Step (IS)           | Claims <u>1-14</u> | YES |
|                               | Claims <u>NONE</u> | NO  |
| Industrial Applicability (IA) | Claims <u>1-14</u> | YES |
|                               | Claims <u>NONE</u> | NO  |

## 2. citations and explanations (Rule 70.7)

Claims 1-14 meet the criteria set out in PCT Article 33(2)-(4) because the prior art does not teach or fairly suggest the claimed invention. The methods have industrial applicability as clinical assays.

The closest prior art, McGraw et al. teaches the use of a receptor having single nucleotide polymorphisms at nucleotides 46 and 79. McGraw et al. neither teaches nor suggests the claimed use of a beta-2 adrenergic receptor having a polymorphism at position 491. Also McGraw does not teach or suggest the use of the Ile 164 receptor in view of the unexpected property of reduced exosite binding and shorter duration of action to the beta-agonist salmeterol used in disease treatment.

----- NEW CITATIONS -----  
NONE